

Translation

PATENT COOPERATION TREATY

PCT/EP2003/004030



PCT

IP# 511, 888

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70) Rec'd PCT/PTO 23 JUN 2005

Applicant's or agent's file reference 29799P WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/004030	International filing date (day/month/year) 17 April 2003 (17.04.2003)	Priority date (day/month/year) 19 April 2002 (19.04.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/127		
Applicant BIOGHURT BIOGARDE GMBH & CO. KG.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.  <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <u>2</u> sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 06 November 2003 (06.11.2003)	Date of completion of this report 25 August 2004 (25.08.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/004030

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-12 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_ 2-4, 6-12 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_ 1, 5, 13 \_\_\_\_\_, filed with the letter of \_\_\_\_\_ 19 March 2004 (19.03.2004)
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/04030

## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

The amendments submitted with the letter of 19 March 2004 introduce substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed.

The passage on page 9, line 30, cannot be a basis for the following amendment in claim 1:

- that (the final matrix) is pasty.

This amendment therefore will not be taken into account during further examination proceedings.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims		YES
	Claims	1-13	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

### 2. Citations and explanations

#### 1. Cited documents

This report makes reference to the following documents:

D1: WO-A-0184961

D2: WO-A-9321190

D3: WO-A-9211294

#### 2. Desirable result (PCT Article 6)

Claim 1 does not meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. The claim attempts to define the subject matter in terms of the result to be achieved, namely:

- and the additional matrix components being selected in such a way that the final matrix is solid at room temperatures and has the property of shear thinning; but in so doing merely states the problem to be solved, without specifying the technical features necessary for achieving this result.

Such wording is not admissible in the present case because it seems possible to describe the subject matter of the application more concretely, i.e. to specify the matrix components.

This amendment therefore will not be taken into account of during further examination proceedings.

### 3. Novelty (PCT Article 33(2))

When assessing the novelty of the subject matter of a claim, statements regarding an intended, special type of use (for example, "as a bioactive component", claim 1) are not to be taken into account.

D1 (see page 13, example 1 and claims 1 to 18) discloses a capsule for use in the treatment of dementia, containing: a/ 15.6% w/w phosphatidylcholine (PC), b/ 14.5% w/w phosphatidylserine (PS), c/ 15.1% w/w omega-3 fatty acid and d/ 24.1% w/w vitamin E. The subject matter of claims 1 to 13 is therefore not novel (PCT Article 33(2)).

D2 (see pages 37 and 38, example 7) discloses a capsule for treating symptoms of pathologies of the central nervous system, said capsule containing PC and PS and having an outer shell containing gelatin and glycerol. The subject matter of claims 1, 3, 4 and 11 to 13 is therefore not regarded as novel (PCT Article 33(2)).

D3 (see example 2.1 on page 36) relates to a tablet or a capsule containing: a/ 17% w/w new heparin derivative PE, b/ 45.5% w/w PC + PS, c/ 28.4% w/w lactose and d/ 5.7% w/w microcrystalline cellulose. The subject matter of claims 1 to 12 is therefore not novel (PCT Article 33(2)).

### 4. Inventive step (PCT Article 33(3))

Since the subject matter of claims 1 to 13 is not novel, it also does not involve an inventive step (PCT Article 33(3)).

**5. Industrial applicability (PCT Article 33(4))**

The subject matter of claims 1 to 13 meets the requirements of PCT Article 33(4) with regard to industrial applicability.